EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	Master File No. 2:12-MD-MDL 2327
THIS DOCUMENT RELATES TO THE CASES LISTED BELOW	:	JOSEPH R. GOODWIN US DISTRICT JUDGE

Mullins, et al. v. Ethicon, Inc., et al. 2:12-cv-02952
Sprout, et al. v. Ethicon, Inc., et al. 2:12-cv-07924
Iquinto v. Ethicon, Inc., et al. 2:12-cv-09765
Daniel, et al. v. Ethicon, Inc., et al. 2:13-cv-02565
Dillon, et al. v. Ethicon, Inc., et al. 2:13-cv-02919
Webb, et al. v. Ethicon, Inc., et al. 2:13-cv-04517
Martinez v. Ethicon, Inc., et al. 2:13-cv-04730
McIntyre, et al. v. Ethicon, Inc., et al. 2:13-cv-07283
Oxley v. Ethicon, Inc., et al. 2:13-cv-10150
Atkins, et al. v. Ethicon, Inc., et al. 2:13-cv-11022
Garcia v. Ethicon, Inc., et al. 2:13-cv-14355

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October 6, 2015
Deposition of Elaine Duncan

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CAPTION CONTINUED:
Lowe v. Ethicon, Inc.,
et al. 2:13-cv-14718
Dameron, et al. v. Ethicon, Inc.,
et al. 2:13-cv-14799
Vanbuskirk, et al. v. Ethicon, Inc.,
et al. 2:13-cv-16183
Mullens, et al. v. Ethicon, Inc.,
et al. 2:13-cv-16564
Shears, et al. v. Ethicon, Inc.,
et al. 2:13-cv-17012
Javins, et al. v. Ethicon, Inc., .
et al 2:13-cv-18479
Barr, et al. v. Ethicon, Inc., .
et al 2:13-cv-22606
Lambert v. Ethicon, Inc.,
et al. 2:13-cv-24393
Cook v. Ethicon, Inc.,
et al. 2:13-cv-29260
Stevens v. Ethicon, Inc.,
et al. 2:13-cv-29918
Harmon v. Ethicon, Inc.,
et al. 2:13-cv-31818
Snodgrass v. Ethicon, Inc.,
et al. 2:13-cv-31881
Miller v. Ethicon, Inc.,
et al. 2:13-cv-32627
Matney, et al. v. Ethicon, Inc.,
et al. 2:14-cv-09195
Jones, et al. v. Ethicon, Inc.,
et al. 2:14-cv-09517
Humbert v. Ethicon, Inc.,
et al. 2:14-cv-10640
Gillum, et al. v. Ethicon, Inc.,
et al. 2:14-cv-12756
Whisner, et al. v. Ethicon, Inc.,
et al. 2:14-cv-13023
Tomblin v. Ethicon, Inc.,
et al. 2:14-cv-14664
Schepleng v. Ethicon, Inc.,
et al. 2:14-cv-16061
Tyler, et al. v. Ethicon, Inc.,
et al. 2:14-cv-19110

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CAPTION CONTINUED:
Kelly, et al. v. Ethicon, Inc., et al. 2:14-cv-22079
Lundell v. Ethicon, Inc., et al. 2:14-cv-24911
Cheshire, et al. v. Ethicon, Inc., et al. 2:14-cv-24999
Burgoyne, et al. v. Ethicon, Inc., et al. 2:14-cv-28620
Bennett, et al. v. Ethicon, Inc., et al. 2:14-cv-29624

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October 6, 2015

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DEPOSITION OF ELAINE DUNCAN, taken pursuant to notice, was held at the law offices of Nilan Johnson Lewis, PA, 120 South Sixth Street, Suite 400, Minneapolis, Minnesota 55402, commencing at 9:15 a.m. on the above date, before Barbara J. Carey, Registered Professional Reporter and Notary Public in and for the State of Minnesota.

sitting here today with the benefit of hindsight, which of course we do --

A. 20/20.

Q. -- always 20/20.

Is there anything that you would recommend today to Ethicon that would have changed that design qualification back in the late '90s, early 2000s?

A. It's my conclusion that this device, based on the clinical experience and the robust endorsement of this device by the AUGS organization, and even the FDA, that I would be foolhardy to try to suggest there's a better way to make this product.

Q. Okay. So let me ask -- because I think we're maybe talking about two different things here.

AUGS was not involved in the design process or the qualification of the design of the TVT-R mechanically-cut mesh; correct?

A. Physicians were certainly incorporating their ideas, yes.

Q. Okay. But you specifically mentioned the AUGS.

A. Uh-huh.

Q. And you'll agree with me that AUGS had nothing to do with the qualification of the design of the TVT-R

you're not qualified to talk -- about the clinical, the medical risk and benefit of the TVT-R mechanically-cut device today; correct?

A. But ma'am, you asked me -- I think if you go back to the question, it was "Would there be a better way of doing it?" And I have to say, again, that the proof is in the pudding, that when we look at a device, which is functioning as intended and safe, I would not recommend to a company to go back and redesign it.

Q. And perhaps we're talking about something different. I think this is what I'm trying to get at with you.

A. Okay.

Q. I'm not talking about going back and redesigning.

A. Okay.

Q. There's a process that every company has to go through when designing a medical device; correct?

A. They vary, but as a general framework, we currently do, yes.

Q. Okay. And the reason the process is in place is ultimately to ensure patient safety; correct?

A. That's the goal, yes.

Q. And you believe that it's important for

their output in the context of what was happening at the time I'm looking. So if I'm looking at due diligence of a license, I look at what's current at that time with respect to procedures that derive from standards in guidance documents and regulations.

Q. Okay. You keep giving me the same answer.

A. It's the same answer?

Q. Well, you're not answering the question.

A. I'm sorry, I'm trying my best.

Q. So let me try this again.

MR. DAVIS: Object to the form.

MR. WALLACE: You're talking over her.

THE WITNESS: Thank you.

BY MS. FITZPATRICK:

Q. Can you do what you did in this report without looking at and considering the FDA regulations concerning medical devices?

A. You have to consider them.

Q. Okay. And you considered the FDA regulations concerning medical devices in your report and in your opinions that you reached in this case; right?

A. As one of many things that I considered.

Q. And you're not able to issue this report without considering the FDA regulations.

Is that your testimony?

A. No, I could go back and revise the report and leave out FDA regulations, but it would be less than a diligent job on my part because I have to be present with respect to standards and regulations and best practices that are current in each of these phases.

So if you would want me to go back and revise the report, for example, and take out just FDA regulations, it would be peculiar, at best.

Q. Would it be a different report?

A. I can't say without attempting to do it. It wouldn't be what I normally do as a part of due diligence.

Q. Okay. And it wouldn't be --

A. Can I give you an example?

Q. Hang on. Yes, you can, but let me make sure that I'm understanding.

A. Okay.

Q. Because you and I seem to have lost --

A. Our rapport?

Q. I don't want to say rapport, but we seem to be talking past each other.

The report, as drafted, has intertwined throughout it consideration of the FDA requirements for medical devices; correct?

A. In connection with. I'm just trying to understand what you mean by "in connection with."

Q. As opposed to the TVT-O, as opposed to the Prolift. We're talking -- you do understand we're here talking about what Ethicon did with respect to the TVT-R product? You understand that; right?

A. Now, you said it differently. You said -- so I can state myself that I believe they did their due diligence for the product in each of the respective phases that I reviewed for mechanical.

Q. And one of the things that you rely on to reach that conclusion concerning due diligence is the fact that Ethicon received a number of 510(k) clearances for the TVT products?

A. It was only one of the things that I looked at. I didn't rely on it exclusively.

Q. Okay. Perhaps you want to listen to my question.

One of the things that you rely on to reach that conclusion concerning due diligence is the fact that Ethicon received a number of 510(k) clearances for the TVT products?

A. The family of products. That was one of the things I looked at.

Q. And that's what I asked you. So the answer is "yes"?

A. Yes.

Q. And you go on in your report to say, "Despite the impression created by the lay press, a 510(k) submission is NOT" -- and you've got that capitalized, -- "a 'shortcut to market.'"

What lay press are you referring to?

A. Any of the lay press. There's constantly -- I live in an area where medical device companies are concentrated, so the Star Tribune and the Pioneer Press and any -- even the New York Times will often refer to a 510(k) as the shortcut process for FDA approval, and that's the point I was trying to make.

Q. You -- do you believe that there's a difference between the requirements for PMA versus 510(k) clearance by the FDA?

A. It's not a belief; it's a fact.

Q. Okay. And you'll agree with me that the 510(k) submission takes a shorter period of time to get a product to market; correct, than a PMA?

A. Not always.

Q. Okay. Give me an example of when a PMA took a shorter period of time to get something to market than the

in order to do a comprehensive due diligence, and I did my best to do that throughout the effort that I put into this report.

BY MS. FITZPATRICK:

Q. Is it -- I'm trying to understand what you're saying.

Are you saying that you could not do a comprehensive due diligence without considering the FDA regulations in connection with this report?

A. It would be less than professional.

Q. Okay.

MR. DAVIS: At some point, let's take a break, but you can finish this line.

MS. FITZPATRICK: Yeah, let me just finish this; okay?

BY MS. FITZPATRICK:

Q. And because of your opinion on that, you mentioned -- in assuming the three -- I don't know where it is -- you said three of that pyramid.

One of the three things that is the cornerstone or that you considered is compliance by Ethicon with FDA regulations. It's one of the three?

MR. DAVIS: Object to the form.

THE WITNESS: All regulations, whether